

EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Lawrence Maxcy, individually
and on behalf of those similarly
situated,

Court File No. 15-cv-2210 (PJS/BRT)

Plaintiff,

vs.

Paul Schnell, in his official
capacity as the Commissioner of
the Minnesota Department of
Corrections, et al.,

Defendants.

SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement (“Agreement”) is entered into between the following Parties: the individual and class Plaintiffs (collectively “Plaintiffs”) and Defendants Paul Schnell, in his official capacity as Commissioner of the Minnesota Department of Corrections (“DOC”), David Paulson, in his official capacity as Medical Director of the DOC, Nanette Larson, in her official capacity as Health Services Director of the DOC (collectively “Defendants”).

RECITALS

WHEREAS, this Settlement Agreement arises out of an action brought by Plaintiff Lawrence Maxcy, on behalf of himself and other similarly situated prisoners who are in Minnesota Correctional Facilities (*Lawrence Maxcy, individually and on behalf of those similarly situated v. Paul Schnell, in his official capacity as the*

Commissioner of the Minnesota Department of Corrections, et al., Court File No. 15-cv-2210 (PJS/BRT), alleging that the DOC, under its Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection, fails to provide necessary medical care to all prisoners with Chronic Hepatitis C, in violation of the Eighth Amendment of the United States Constitution and the Americans with Disabilities Act (“ADA”).

WHEREAS, the Court granted Plaintiffs’ Motion for Class Certification (Dkt. No. 238) and certified a class defined as “all current and future inmates of Minnesota correctional facilities who have been diagnosed with chronic hepatitis C and have not received treatment with a direct-acting antiviral medication.” (Dkt. No. 317);

WHEREAS, the Parties, without conceding any infirmity in their claims or defenses, have engaged in extensive, arms-length negotiations concerning the claims raised in this litigation and have concluded that it is in their mutual best interest to fully and finally resolve and settle any and all past, existing, and/or potential injunctive and equitable claims between Plaintiffs and Defendants relating to Hepatitis C treatment.

WHEREAS, Defendants deny and continue to deny any and all liability or wrongdoing to Plaintiffs, and do not admit any wrongdoing or liability of any kind, including the claims raised in the Third Amended Complaint, and expressly deny the same. Nor does the DOC concede that class certification is appropriate. The Parties agree that this Agreement does not constitute evidence of an admission of any liability, omission, or wrongdoing of any kind by the Defendants, the State of Minnesota, or any former or current employee, official, or agent of the DOC.

NOW, THEREFORE, the Parties, intending to be legally bound and in consideration of the mutual covenants and other good and valuable consideration, the sufficiency of which is hereby acknowledged and set forth below, hereby agree as follows:

DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

1. “**Action**” means the above-captioned matter.
2. “**April 2018 Guidelines**” mean the Minnesota Department of Corrections’ “Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection” adopted April 2018, and attached hereto as Exhibit A.
3. “**Third Amended Complaint**” means the Third Amended Complaint filed in this Action (Dkt. No. 205) filed on or about December 10, 2017.
4. “**Class Counsel**” means Michael V. Ciresi, Katie Crosby Lehmann, Andrew H. Mohring, and Esther O. Agbaje of Ciresi Conlin LLP, Peter J. Nickitas, and C. Peter Erlinder.
5. “**Class Members**” mean “all current and future inmates of Minnesota correctional facilities who have been diagnosed with chronic Hepatitis C and have not received treatment with a direct-acting antiviral medication,” as defined in the Court’s order certifying a class (Dkt. No. 322).
6. “**Class Representative**” means Plaintiff Lawrence Maxcy.
7. “**DAAs**” means the class of medications known as Direct-Acting Antivirals, approved by the U.S. Food and Drug Administration and used to treat Hepatitis C.

8. “**DOC**” means the Minnesota Department of Corrections, as established by Minnesota Statutes, sections 15.01 and 241.01, or its successor agency.

9. “**Effective Date**” means the date upon which the District Court in this Action gives Final Approval to the Agreement and the time to appeal the Final Approval has expired; or, if an appeal is filed, final adjudication or resolution of the same.

10. “**Fairness Hearing**” means the hearing under Fed. R. Civ. P. 23(e)(2).

11. “**Fee Award**” means the amount of attorneys’ fees and reimbursement of expenses and costs awarded by the Court to Class Counsel.

12. “**Final Approval**” means the Court’s entry of this Agreement as an Order of the Court following the Fairness Hearing.

13. “**HCV**” means Hepatitis C, a viral infection.

14. “**Minnesota Correctional Facility**” means a state correctional facility under the control of the Minnesota Commissioner of Corrections, including the facilities in Faribault, Lino Lakes, Oak Park Heights, Red Wing, Rush City, Shakopee, St. Cloud, Stillwater, Togo, and Willow River/Moose Lake.

15. “**Notice**” means the Notice of Class Settlement described in Section VI below.

16. “**Notice Documents**” means a summary letter from Lead Class Counsel and Notice from the Court, attached hereto as Exhibit C.

17. “**Prisoner**” means an individual committed to the custody of the Commissioner of the DOC and who is confined in a Minnesota Correctional Facility.

18. **“Updated Guidelines”** means the revised Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection that will be drafted to incorporate the terms of this Agreement.

AGREEMENT

I. AMENDMENT OF THE 2018 GUIDELINES

A. No later than 60 days after the Effective Date, the DOC shall revise the 2018 April Guidelines and replace them with Updated Guidelines.

B. The Updated Guidelines shall include the following practices already contained in the April 2018 Guidelines:

1. At intake, all prisoners shall be screened for HCV on an opt-out basis. Blood tests for HCV shall include a screening blood test for the HCV antibody and, if that test is positive, a confirmatory test for HCV virus to determine whether there is an active infection.

Nursing Staff will:

- a. Explain risk factors for HCV infection and methods of transmission of HCV to prisoners;
- b. Inform prisoners that the DOC tests all offenders for Hepatitis C at intake unless the prisoner declines (opts out) of the test;
- c. Order the HCV blood test unless the prisoner declines the test;
- d. Provide education and written information on HCV transmission, the progression of HCV infection, potential

health complications of HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated in the DOC;

- e. Explain procedures for following up on HCV tests; and
- f. Inform prisoners who decline the intake test that they may request the HCV test at a future time.

2. All prisoners who, while in prison, have a positive test indicating an active Hepatitis C infection will be offered an initial evaluation with a medical practitioner as follows:

- a. The initial visit shall not be subject to a co-payment.
- b. Laboratory testing shall be performed either prior to or during the initial visit, and will include the following tests:
 - i. Complete blood count (“CBC”);
 - ii. Complete metabolic profile (“CMP”);
 - iii. International normalized ratio (“INR”);
 - iv. HIV antigen/antibody test;
 - v. Hepatitis B surface antigen, surface antibody, and Hepatitis B core antibody testing;
 - vi. Hepatitis A antibody;
 - vii. Additional testing that the practitioner determines are indicated.
- c. The initial practitioner visit shall include:

- i. A targeted history and physical exam;
 - ii. An order for immunization for Hepatitis A and B, if indicated;
 - iii. Order for pneumococcal vaccine, if the prisoner shows evidence of cirrhosis; and
 - iv. Explanation of the process for scheduling periodic evaluations and criteria for determining treatment eligibility.
3. Staging of prisoners who have a positive test using ultrasound elastography or other medically appropriate staging test such as liver biopsy, blood tests, physical examination, magnetic resonance imaging, or computerized tomography.
4. Antiviral treatment with DAAs for the following prisoners who have HCV and:
 - a. Fibrosis stages 2, 3, and 4, as determined by ultrasound elastography or other recognized staging method;
 - b. Concurrent chronic hepatitis B or HIV infection;
 - c. Extrahepatic manifestations of chronic HCV infection such as cryoglobulinemia or significant renal insufficiency, clinically defined as GFR less than or equal to 59mL/min. per 1.73 square meters;

- d. Were admitted to prison while receiving uninterrupted and documented HCV antiviral treatment;
 - e. Have had a liver transplant;
 - f. Have been diagnosed with hepatocellular carcinoma or other malignancies;
 - g. Have been diagnosed with comorbid liver disease, such as autoimmune hepatitis, hemochromatosis, or non-alcoholic steatohepatitis (NASH); or
 - h. Diabetes mellitus.
5. Any prisoner who has HCV and is ineligible for antiviral treatment with DAAs under Sections I.B.4 or I.C.1.a shall be allowed to request evaluation of his or her condition every 6 months or more often if recommended by the prisoner's practitioner. The periodic evaluations shall not be subject to a co-payment. The periodic evaluations shall generally consist of:
- a. An interim targeted history and physical exam;
 - b. Laboratory testing, CBC, CMP, and INR; and
 - c. Other testing as clinically indicated.
6. Prisoners will be excluded or deferred from treatment under any of the following conditions or situations:
- a. Contraindications based on drug interactions or concurrent medical conditions;

- b. Planned medical treatment, such as surgery, that may interfere with the medication or continuity of treatment with DAAs;
- c. Life expectancy of less than 18 months;
- d. Inability or unwillingness to adhere to or cooperate with the treatment or clinical monitoring;
- e. Pregnancy; or
- f. Evidence of active intravenous drug use.

C. The April 2018 Guidelines shall be revised to include the following additional provisions:

- 1. Antiviral treatment with DAAs will be provided for prisoners whose elastography or other staging test indicates that they are at:
 - a. Fibrosis stage 1; or
 - b. Fibrosis stage 0, provided that the prisoner has been in a Minnesota Correctional Facility for a continuous period of 16 months, and has 24 weeks or more remaining in prison.
- 2. Prisoners with an APRI score greater than 2.0 or a FIB4 score greater than 3.25 at a follow-up evaluation will be offered an ultrasound elastography for restaging. Should the elastography study show that the prisoner has stage 1, 2, 3, or 4 fibrosis, the prisoner will be treated with antivirals, provided that the prisoner has at least 24 weeks remaining on his or her current term of

imprisonment and none of the exclusions under the Updated Guidelines apply.

3. Antiviral treatment for prisoners who are eligible for DAAs under the Updated Guidelines shall begin within 3 months of determination of the prisoner's fibrosis levels 1-4 or fibrosis stage 0 and any of the co-occurring conditions identified *supra* at Section I.B.4 of this Agreement.

D. The DOC shall begin to treat the individuals identified *supra* at Section I.C.1.b of this Agreement within 6 months of the Effective Date. The DOC shall implement all other provisions the Updated Guidelines within 60 days of the Effective Date.

II. EDUCATION FOR PRISONERS AT RELEASE

Prisoners with HCV who are released from a Minnesota Correctional Facility and who have not received antiviral treatment will be provided with the information appearing in the document attached hereto as Exhibit B, with the information about treatment facilities and coverage to be updated every six months. This provision will become effective within 60 days of the Effective Date.

III. TERM OF THE AGREEMENT

- A. The Court will retain jurisdiction over the settlement for a 24-month period from the Effective Date, at which time the Court's jurisdiction shall terminate.

- B. The DOC's obligations under this Agreement shall expire at the end of 24 months from the Effective Date. Upon termination, the Parties will sign and submit a joint stipulation of dismissal with prejudice, pursuant to Rule 41(a) of the Federal Rules of Civil Procedure, thereby ending the Court's jurisdiction over this case.

IV. MONITORING

While the Court retains jurisdiction, the DOC shall file quarterly reports with the Court and Class Counsel within 6 weeks of the end of each quarter of the State's fiscal year. These reports shall document any changes to the Updated Guidelines and, without reference to a prisoner's name or offender identification number, the number of prisoners, by fibrosis level, who have been: 1) tested for HCV, 2) diagnosed with HCV through a positive PCR test, and 3) treated or untreated with antivirals. The quarterly reports shall also identify the basis for deferral or denial of antiviral treatment to any prisoner who would otherwise qualify under the Updated Guidelines, as outlined at paragraphs I.B 4., and I.C.1., above.

V. PRELIMINARY APPROVAL

As soon as practicable following the execution of this Agreement, counsel for the Parties shall apply to the Court for a preliminary order:

- A. Granting preliminary approval of this Agreement for the purposes of disseminating Notice to prisoners who are Class Members;
- B. Approving the form, contents, and dissemination of the Notice of this Agreement to prisoners who are known to be Class Members; and

- C. Scheduling a Fairness Hearing to review comments and/or objections regarding this Agreement, consider the fairness, reasonableness, and adequacy of this Agreement, and consider whether the Court should order Final Approval of this Agreement and grant Class Counsel's requested Fee Award.

VI. NOTICE TO THE CLASS OF THE PROPOSED SETTLEMENT

A. Form of Notice. The Notice Documents shall be in the form agreed to by the Parties and attached as Exhibit C.

B. Dissemination of Notice. Within 21 days of the date of Preliminary Approval the DOC shall provide Notice of this Agreement by:

1. Delivery of the Notice Documents to Class Members, within 21 days of the date of Preliminary Approval.
2. Posting the Notice Documents in a conspicuous place in all living units at Minnesota Correctional Facilities and the Transitional Care Unit at the Minnesota Correctional Facility at Oak Park Heights until 42 days after the date of Preliminary Approval, beginning within 21 days of the date of Preliminary Approval;
3. Providing a copy of the Notice Documents to all prisoners in restrictive housing units or who need it in alternative formats;
4. Posting the Notice Documents in a conspicuous location in the Health Services Area of each DOC facility until 42 days after the

date of Preliminary Approval, beginning within 21 days of the date of Preliminary Approval; and

5. Posting a copy of this Agreement in the Health Services Area of each DOC facility and library accessible to Class Members for the period of this Agreement

C. Objections to Settlement. As set forth in the Notice, any Class Member may object to this Agreement by submitting their objection to Class Counsel in writing, via regular or electronic mail, or by contacting Class Counsel in writing at the mailing address listed at Section X. COMMUNICATIONS, below, no later than a date set by the Court in this case after Preliminary Approval. All objections will be provided to Defendants' Counsel and filed with the Court.

D. The Parties agree that the proposed Notice is reasonably calculated to apprise the Class of the pendency of this Agreement.

VII. THE FEE AWARD

The DOC agrees to pay attorneys Three Hundred and Twenty-Five Thousand Dollars and No Cents (\$325,000.00) in Attorneys' Fees and documented Costs of Forty-One Thousand One Hundred and Forty Four Dollars and Twenty-Five Cents (\$41,144.25). The DOC shall issue payment through an electronic funds transfer within 30 days of the Effective Date of this Agreement. Lead Class Counsel will provide a complete set of receipts in support of this figure and a release of any and all fees and costs from all other counsel. Fees and costs will be reported to Ciresi Conlin, LLP on IRS Form 1099.

VIII. FINAL APPROVAL

This Agreement shall be subject to the Final Approval of the Court. The Parties shall cooperate in presenting this Agreement to the Court for Final Approval and/or or at any hearing under Rule 23(e) of the Federal Rules of Civil Procedure. At the Fairness Hearing, the Parties will jointly move for Final Approval of this Agreement as fair, adequate, and reasonable. If the Court does not grant Final Approval, this Agreement shall be null and void and of no force and effect, and nothing herein shall be deemed to prejudice the position of any Party with respect to the Action or otherwise, and neither the existence of this Agreement, nor any of its terms or provisions, nor any of the negotiations or proceedings connected with it, shall be admissible in evidence, referred to for any purpose in this Action or in any other litigation or proceeding, or construed as an admission, presumption, or concession by any Defendant of any liability or the truth of any of the allegations in the Action, or by Plaintiff of any vulnerability or defect in his claims.

IX. RELEASE

In consideration of the terms and conditions herein, the Parties agree that this Agreement represents a full and fair resolution of the claims for relief alleged in the Third Amended Complaint. Plaintiffs' release includes all claims for injunctive or declaratory relief, and any claims for related costs and attorneys' fees (except as provided in Section VII above), which Class Members had or may have related to the treatment of Hepatitis C while in prison or the allegations in the Third Amended Complaint.

The Parties will execute a separate full and final release as to attorneys' fees and costs to be signed by all counsel of record.

X. COMMUNICATIONS

Any notice, report, or communication required or permitted to be given to Class Counsel or Defendant(s) under this Agreement shall be given in writing by email and U.S. Mail, addressed as follows:

To Class or Class Counsel:

Hepatitis C Class Action
Ciresi Conlin LLP
225 South Sixth Street, Suite 4600
Minneapolis, MN 55402
(612) 361-8230
ahm@ciresiconlin.com

To Defendants:

Kathryn Fodness
Assistant Attorney General
445 Minnesota Street, Suite 1100
St. Paul, MN 55101
(651) 757-1348
Kathryn.Fodness@ag.state.mn.us

Either Party may substitute the individual designated to receive notice by advising the other side in writing by email and U.S. Mail.

XI. NON-ADMISSION OF LIABILITY

It is expressly understood that nothing in this Agreement shall constitute nor be construed to be an admission of any wrongdoing or liability, nor an admission that class certification is appropriate. The DOC specifically disclaims any liability or wrongdoing on the part of the DOC, its agents, and employees.

XII. RELEASE OF INFORMATION

The Parties understand that the release of information by the Minnesota Department of Corrections, or any other agency or department of the State of Minnesota, about this matter is governed by Minn. Stat. § 13.01, et seq. (“Minnesota Government Data Practices Act”) and Minn. Stat. § 15.17, et seq. (“Official Records Act”). The Parties agree that the specific reasons that this dispute is being settled include: (1) to avoid any and all further costs of litigation for all parties; and (2) to avoid any and all further risks of litigation for all parties.

XIII. REPRESENTATION

Each Party represents and acknowledges that each Party is and has been represented by its own counsel. Each Party represents and acknowledges that, in executing this Agreement, no Party relies or has relied upon any representations or statements made by any other Party or its counsel other than the promises set forth in this Agreement. Each Party acknowledges that each Party has carefully read the entire Settlement Agreement, has been given the opportunity to consult with and be advised by their attorney, and knows and understands the contents of this Settlement Agreement.

XIV. GOVERNING LAWS

This Agreement is to be interpreted and enforced in accordance with the laws of the State of Minnesota.

XV. COUNTERPARTS

This Settlement Agreement shall become effective upon its execution, subject to subsequent Court approval. The Parties may execute this Settlement Agreement in

counterparts, and execution in counterparts shall have the same force and effect as if the Parties had signed the same instrument. Any signature made and transmitted by facsimile for the purpose of executing this Settlement Agreement shall be deemed an original signature for purposes of this Settlement Agreement and shall be binding upon the signing Party.

XVI. ENTIRE AGREEMENT

This Settlement Agreement constitutes the entire agreement of the Parties concerning the subjects contained herein, and no modification of this Agreement and/or other promises or agreements shall be binding unless in writing and signed by all the Parties hereto, except that the Class Representative expressly authorizes Class Counsel to enter into such modifications or amendments to this Agreement on behalf of the Class Members as Class Counsel deem appropriate, subject to the approval of the Court.

Dated: March 14, 2019

By: /s/ Andrew H. Mohring
Michael V. Ciresi (MN #0016949)
Katie Crosby Lehmann (MN #0257357)
Andrew H. Mohring (MN #0190731)
Esther O. Agbaje (MN#0399145)
Ciresi Conlin LLP
225 South 6th Street, Suite 4600
Minneapolis, MN 55402
Telephone: 612.361.8200
AHM@CiresiConlin.com
EOA@CiresiConlin.com
LEAD COUNSEL FOR PLAINTIFF AND CLASS

Dated: March 14, 2019

By: /s/ Peter J. Nickitas
Peter J. Nickitas (MN #0212313)
Peter J. Nickitas Law Office, LLC
431 S. 7th St., Suite 2446
Minneapolis, MN 55415-1854
peterjnickitaslawllc@gmail.com

Dated: March 14, 2019

By: /s/ Carl Peter Erlinder
Carl Peter Erlinder (MN #0398765)
Law Office of Carl Peter Erlinder
1043 Grand Avenue, Suite 28
St. Paul, MN 55104
651.271.4616
proferlinder@gmail.com

ATTORNEYS FOR PLAINTIFF AND CLASS

THE MINNESOTA DEPARTMENT OF
CORRECTIONS

Dated: March 14, 2019

By: /s/ Michelle Smith
Michelle Smith
Deputy Commissioner, Facility Division

Dated: March 14, 2019

KEITH ELLISON
Attorney General
State of Minnesota

/s/ Kathryn A. Fodness

KATHRYN A. FODNESS
Assistant Attorney General
Atty. Reg. No. 0392184

KELLY S. KEMP
Assistant Attorney General 0220280

445 Minnesota Street, Suite 1100
St. Paul, Minnesota 55101-2128
(651) 757-1348 (Voice)
(651) 282-5832 (Fax)
kathryn.fodness@ag.state.mn.us

ATTORNEYS FOR DEFENDANTS

Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection

The purpose of these guidelines is to provide guidance to health services staff when:

- Screening and testing offenders to determine whether they have a chronic hepatitis C virus (HCV) infection;
- Determining the stage of liver fibrosis in offenders with chronic hepatitis C infection
- Identifying risk factors that are associated progression of fibrosis in those with chronic HCV
- Evaluating HCV infected offenders for treatment with antiviral agents;
- Counseling offenders with chronic HCV; and
- Monitoring the condition of HCV infected offenders before, during and after antiviral treatment.

These guidelines will be updated periodically in accordance with treatment recommendations by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD)/Infectious Disease Society of America (IDSA), the Federal Bureau of Prisons, and other recognized authorities as new treatment strategies and medications are developed.

Background

Hepatitis C is a viral infection most often transmitted by exposure to human blood or body fluids. The most common mode of transmission is through the use of contaminated needles associated with intravenous drug use. Others modes of transmission include sexual, nasal inhalation of drugs, tattooing using unsterile techniques, and getting contaminated blood or body fluids into open wounds or onto mucous membranes. HCV is not transmitted by casual contact such as touching, sharing household items, or by food.

Acute HCV infection is seldom diagnosed because it usually causes few symptoms, therefore the person does not seek medical evaluation. About 25% of acute cases spontaneously resolve without anti-viral treatment. The remainder of cases develop chronic HCV infection. Chronic HCV infection typically is asymptomatic for many years and can only be diagnosed by blood testing. Over time chronic HCV infection can cause permanent and potentially life threatening liver disease. Progression to advanced liver disease is a slow process generally taking 20-25 years. . The most important factor in causing liver disease progression is excessive alcohol consumption. Other factors for progression include co-infection with human immunodeficiency virus (HIV) and hepatitis B virus (HBV) infection.

Goals

The goals of the Department in establishing these HCV guidelines are as follows:

- To identify offenders infected with HCV;
- To provide appropriate education and counseling to offenders on the nature of the disease and its transmission and how to prevent disease progression;
- To identify those offenders that are most likely to experience life altering or threatening complications of HCV so they can receive antiviral treatment;
- To provide appropriate antiviral treatment to these offenders; and
- To prevent spread of HCV through education and treatment.

1. Intake screening and testing for HCV Infection

At intake, DOC nursing staff will:

- a. Explain risk factors for HCV infection and methods of transmission of HCV to offenders;
- b. Inform the offender that the DOC tests all offenders for hepatitis C at intake unless the offender declines (opts out) of the test;
- c. Order the HCV blood test unless the offender declines the test;
- d. Provide education and written information on HCV transmission, the natural history of HCV infection, potential health implications of HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated in the MN DOC;
- e. Explain procedures for following up on HCV tests; and
- f. Inform offenders who decline the intake test, that they may request the HCV test at a future time.

2. Blood Testing for HCV

- a. Blood tests for HCV include a screening blood test for the HCV antibody and, if that test is positive, a confirmatory test for HCV virus to determine whether there is active infection. (The confirmatory test is done as a reflex test.)
- b. Offenders who decline intake testing may request HCV blood testing at a later date. Repeat screening tests must be ordered by a practitioner.

3. Evaluating HCV Infected Offenders

Nursing staff will schedule an initial practitioner visit to follow-up on all positive HCV PCR tests (tests indicating active hepatitis C infection). Initial and follow-up care for offenders with HCV infection is not subject to the offender co-payment.

a. Initial Evaluation

Practitioners will conduct an initial evaluation that includes:

- 1) A targeted history and physical exam;

- 2) Laboratory tests including: (these tests may be done prior to the initial visit)
 - Complete blood count (CBC)
 - Complete metabolic profile (CMP)
 - International normalized ratio (INR)
 - HIV antigen/antibody test
 - Hepatitis B surface antigen, surface antibody and hepatitis B core antibody
 - Hepatitis A antibody
 - Additional tests that the practitioner determines are indicated;
 - HCV genotype test may be delayed until antiviral treatment is planned;
 - 3) Order immunization for hepatitis A and B if indicated;
 - 4) Order pneumococcal vaccine, if there is evidence of cirrhosis;
 - 5) Explanation of the process for periodic evaluation and criteria for determining treatment eligibility;
 - 6) Providing the offender with recommendation for frequency of follow-up;
 - 7) Staging elastography will be done on offenders with HCV chronic infection. (This may be done after the initial evaluation.); and
 - 8) When cirrhosis is known, referral for:
 - Endoscopic screening for esophageal varicosities
 - Liver ultrasound (this is done routinely in conjunction with elastography)
- b. Periodic Evaluation of Chronic Infection
- Offenders with chronic HCV will be evaluated periodically to monitor for the progression of liver disease and other complications.
- 1) Offenders are responsible for requesting periodic evaluations of their condition. Generally, re-evaluation should be done every 6 months or more often if the practitioner recommends this.
 - 2) Practitioners at the facilities will conduct the periodic evaluations, which will generally consist of:
 - a) An interim targeted history and physical exam;
 - b) Laboratory testing, CBC, CMP, and INR;
 - c) Ultrasound screening for liver cancer every 6 months for offenders with stages 3 and 4 fibrosis
(This screening is indicated for both treated and untreated cases.); and
 - c) Other testing as clinically indicated including repeat liver elastography (see 8 below).
- c. Case Reports
- Practitioners and/or facility staff will:

- 1) Complete a Hepatitis C Case Report after the initial evaluation;
- 2) Complete a new case report after each periodic evaluation; and
- 3) Case report documentation;
 - a) File the case report in the offender's medical record; and
 - b) Send a copy of each case report and to the DOC medical director or designee.

4. Determining the stage of liver fibrosis

- a. Offenders with chronic HCV infection will be offered testing to determine their stage of liver fibrosis (Metavir stage 0-4).
- b. The standard staging test is ultrasound based shear wave elastography and limited abdominal ultrasound. In combination, these two tests determine the stage of fibrosis and can detect other liver conditions including signs of decompensated cirrhosis, fatty liver disease, liver masses and infection. These 2 tests are non-invasive and done as a combined procedure.
- c. Elastography and ultrasound will be prioritized based on AST platelet ratio index (APRI) and Fibrosis 4 (FIB-4) calculations. (These are calculations that estimate the probability of significant liver fibrosis. They do not indicate the degree of liver fibrosis.)
- d. Other tests may be used to determine liver fibrosis stage such as liver biopsy, blood tests, physical examination, magnetic resonance imaging or computerized tomography.

5. Anti-viral Treatment

Based on the Hepatitis C Case Reports and additional clinical information, the DOC Medical Director or designee may authorize patient-specific antiviral treatment for offenders who have chronic HCV infection.

(Note: Acute HCV infection is seldom diagnosed because the symptoms are generally mild and non-specific. Anti-viral treatment is not indicated for acute cases, since a substantial proportion spontaneously resolve.)

- a. Only medications approved by the Food and Drug Administration (FDA) will be used for HCV treatment.
- b. In the absence of an exclusion or deferral condition(s) noted below, the DOC will provide HCV antiviral treatment to offenders who have;
 - Fibrosis stages 2, 3 and 4;
 - HCV and concurrent chronic hepatitis B or HIV infection;
 - Certain other co-morbid conditions or extra-hepatic manifestations of chronic HCV infection such as cryoglobulinemia or significant renal insufficiency;
 - Sufficient incarceration time to complete the course of treatment;

- Been admitted to DOC receiving uninterrupted and documented HCV anti-viral treatment;
 - Had a liver transplant;
 - Hepatocellular carcinoma;
 - Certain other malignancies;
 - Co-morbid liver disease [e.g. autoimmune hepatitis, hemochromatosis or non-alcoholic steatohepatitis (NASH)];
 - Renal insufficiency with GFR less than or equal to 59mL/min per 1.73 square meters; and
 - Diabetes mellitus.
 - The Medical Director may make exceptions to the above factors on a case by case basis.
- c. Exclusion or deferral from treatment. The following conditions or situations are indications for deferral of anti-viral treatment:
- Contraindications based on drug interactions or concurrent medical conditions;
 - Planned medical treatment, such as surgery, that may interfere with the medication or continuity of HCV treatment;
 - Life expectancy of less than 18 months;
 - Inability or unwillingness to adhere or cooperate with the treatment or clinical monitoring;
 - Current pregnancy;
 - Evidence of active IV drug use.

6. Treatment regimens

- a. Anti-viral treatment will be consistent with current treatment recommendations established by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD), FBOP, FDA, and/or others.
- b. Patient specific factors in medication selection include:
 - Virus genotype;
 - HCV viral load;
 - Fibrosis stage;
 - Co-existing medical conditions;
 - Medication interactions (real or possible);
 - Prior HCV treatment history;
 - Known or suspected viral medication resistance;
 - Adherence with previous medical treatment and monitoring; and
 - Cost effectiveness.

- c. HCV anti-viral treatment will be administered as directly observed therapy by nursing staff.

7. Monitoring During and After Anti-viral Treatment

Practitioners and nurses at each facility will monitor treatment to identify medication side effects and toxicity and to ensure that offenders who are receiving anti-viral treatment are adhering to their treatment regimens and monitoring, and to determine the effectiveness of the treatment.

- a. Practitioners will obtain lab tests prior to and during treatment weeks, as established by the lab monitoring guidelines.
- b. Practitioners and/or facility staff will report to the DOC Medical Director all information regarding the effectiveness and/or safety of HCV antiviral treatment, including such examples as:
 - 1) The offender does not comply with the treatment regimen, clinical monitoring or lab testing;
 - 2) The offender has a significant adverse or allergic reaction to a medication that cannot be managed medically;
 - 3) Laboratory tests reveal evidence of treatment failure based on continued presence of HCV virus in the blood lab;
 - 4) The offender is experiencing an adverse effect of treatment based on clinical findings or laboratory testing, or
 - 5) There is evidence that the offender is using illicit drugs or alcohol use during treatment.

8. Monitoring when anti-viral treatment is deferred

- a. Offenders with untreated chronic HCV will be monitored on an ongoing basis for progression of liver disease or development of complications.
- b. Restaging of fibrosis with elastography or equivalent testing will be done on the following schedule:
 - 1) Fibrosis stage 1 - annually
 - 2) Fibrosis stage 0 - every 2 years

April 12, 2018

**Central Office**

1450 Energy Park Drive, Suite 200 | St. Paul, MN 55108
 Main: 651.361.7200 | Fax: 651.642.0223 | TTY: 800.627.3529
www.mn.gov/doc

Recommendations for Offenders with Hepatitis C Preparing for Release

Our records indicate that you tested positive for hepatitis C but were not eligible for treatment during your incarceration. Because the hepatitis C virus can have serious effects on your health over time and because treatment with medicines called direct acting antivirals cures HCV in most people, we recommend you take the following steps to stay healthy longer and protect the health of others as well.

1. Get health care coverage

Health care coverage will be important for you to obtain in order for you to receive professional medical support and treatment for your Hepatitis C diagnosis.

MNsure is Minnesota's health insurance marketplace where individuals and families can shop, compare and choose health insurance coverage that meets their needs. MNsure is the only place you can apply for financial help to lower the cost of your monthly insurance premium and out-of-pocket costs. Most Minnesotans who enroll through MNsure qualify for financial help.

You may qualify for low-cost or free health insurances provided through government-sponsored programs, such as Medical Assistance and MinnesotaCare. If you qualify for and enroll in one of these programs, your health coverage will be managed through the Department of Human Services. To start an application go to www.mnsure.org, or for questions call MNsure Contact Center at 651-539-2099 or 855-366-7873.

If you are not able to complete an application online, you can find a MNsure paper application by visiting your county or tribal human and social service office or visiting the following website: <https://mn.gov/dhs/people-we-serve/adults/health-care/health-care-programs/programs-and-services/adults-apply.jsp>.

Veterans Administration

If you are a veteran, you may be eligible for VA health care. You can explore available health care benefits in person, by phone or mail. More information can be found at <https://www.minneapolis.va.gov/>.

Insurance through an employer

If you get a job, be sure to ask your employer about eligibility for medical and pharmacy coverage.

2. Make an appointment with a doctor

Once you have health care coverage, you will need to find a primary doctor and schedule an appointment. Your insurance company will have information on providers in its network. At your appointment, your doctor may refer you to a specialist in liver diseases (hepatology) or infectious diseases to develop a treatment plan

Because appointments can be brief and because there is often a lot of ground to cover, it is a good idea to be well-prepared. To prepare, try to:

- Review your medical record.
- When you make the appointment, be sure to ask if there is anything you need to do in advance, such as restrict your diet.
- Write down any symptoms you are experiencing, including any that may seem unrelated to the reason for which you scheduled the appointment.

- Make a list of all medications, vitamins or supplements you are taking.
- Consider taking a family member or friend with you. Sometimes it is difficult to remember all the information provided during an appointment. Someone who accompanies you may remember something that you missed or forgot.

Medical records

You may request copies of your relevant medical records prior to your release by sending to the facility Health Services Unit a kite and a voucher to pay for the copies. After you have been released, your doctor may request your relevant medical records by contacting Central Office Records at 651-361-7330.

3. Healthy Lifestyle Changes

We also recommend the following lifestyle changes:

- **Stop drinking alcohol.** Alcohol speeds the progression of liver disease.
- **Avoid medications that may cause liver damage.**
 - Review your medications with your doctor, including over-the-counter medications you take as well as herbal preparations and dietary supplements.
 - Your doctor may recommend avoiding certain medications.
- **Help prevent others from coming in contact with your blood.**
 - Cover any wounds you have and don't share razors or toothbrushes.
 - Don't donate blood, body organs or semen, and advise health care workers that you have the virus.
 - Also tell your partner about your infection before you have sex, and always use condoms during intercourse.

Information in this document was obtained from:

- The Mayo Clinic: <https://www.mayoclinic.org/diseases-conditions/hepatitis-c/diagnosis-treatment/drc-20354284>;
- MNsure: www.mnsure.org;
- The Minnesota Department of Human Services; and
- The State of Minnesota and U.S. Departments of Veterans Affairs: <https://www.minneapolis.va.gov/> and <https://explore.va.gov/health-care>.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

LAWRENCE MAXCY,

Civil No. 15-2210 (PJS/BRT)

Individually, and on behalf of those similarly situated,

Plaintiff,

v.

PAUL SCHNELL,

In his official capacity as Commissioner, Minnesota Department of Corrections;

DAVID A. PAULSON, M.D.,

In his official capacity as Medical Director, Minnesota Department of Corrections;

NANETTE LARSON,

In her official capacity as Health Services Director, Minnesota Department of Corrections,

Defendants.

NOTICE TO THE CLASS OF SETTLEMENT AGREEMENT

This Notice sets forth the basic terms of the class action settlement regarding the provision of medical treatment to inmates in the custody of the Minnesota Department of Corrections (“the DOC”) who are infected with chronic hepatitis C (“HCV”).

I. CASE BACKGROUND

Plaintiff filed this lawsuit, on behalf of himself and other similarly situated prisoners in the custody of the DOC, and brought allegations including that the DOC, under its Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection, fails to provide necessary medical care to prisoners with HCV, in violation of the Eighth Amendment of the United States Constitution and 42 U.S.C. § 1983. Defendants have denied the allegations throughout the case. In the end, the suit did not seek, and the settlement does not award, money damages for the class.

On January 3, 2019, the Court certified a class of plaintiffs. This class is defined as:

All current and future inmates of Minnesota correctional facilities who have been diagnosed with chronic hepatitis C and have not received treatment with a direct-acting antiviral medication.

II. THE SETTLEMENT AGREEMENT

The Parties in this lawsuit have recently entered into a Settlement Agreement and Release (“Settlement Agreement” or “Settlement”). Copies of the Settlement Agreement will be available for review in each institution’s medical facility and library.

If the Court approves the Settlement, the DOC will provide treatment with direct acting antiviral (“DAA”) medication to prisoners with HCV as set forth by the Settlement Agreement. In summary, the core terms include: 1) all HCV-infected prisoners at levels F1 through F4 are eligible for DAA treatment, with treatment beginning within three months of the determination of their fibrosis level; 2) all prisoners at F0 with co-occurring conditions, including but not limited to HIV, hepatitis B, diabetes and others, will also be eligible for DAA treatment; 3) the remaining untreated prisoners with HCV, those at F0 without co-occurring conditions, will receive treatment after continuous imprisonment of sixteen months; 4) untreated prisoners are eligible for reassessment every six months, and if it is determined that they have become eligible for treatment, for example by progressing from F0 to F1, they will receive treatment; 5) prisoners who are released without treatment, including those at F0 whose sentences are less than sixteen months and those whose sentences are too short to allow for treatment, will receive current information about HCV and about antiviral treatment resources in the community. A 6-month phase in period applies to the Settlement’s provisions for treating prisoners at levels F1 – F4 and F0 with a co-occurring condition. To be eligible for treatment, prisoners must have 24 weeks or more of their sentences left to serve.

Some limited exceptions to treatment are detailed in the Settlement Agreement. The Settlement Agreement further provides for a two-year monitoring period, during which the DOC will provide quarterly reports to the Court and Class Counsel. No party admits any wrongdoing or deficiency in their case. Defendants will reimburse class counsel for attorneys' fees in the amount of \$325,000, and for documented costs to the date of settlement of \$41,144.25.

Further details of the settlement terms are in the Settlement Agreement, which is available for review at your institution's library and Health Services Area.

III. PURPOSES OF THIS NOTICE

This Notice is sent to advise you of the pending action, the proposed settlement, and your rights with respect to this action. This Notice is not intended to be, and should not be construed as, an expression of any opinion by the Court as to the truth of the allegations in the litigation or the merits of the claims or defenses asserted.

The Settlement Agreement is under review by the Court, and it will not take effect until and unless it is approved by the Court. If you wish to make objections to or comments in support of the Settlement Agreement, you should submit an explanation in writing why you do or do not believe that the Settlement Agreement is fair, reasonable and adequate. You should indicate whether your objections apply only to you, to a specific subset of the class, or to the entire class, and should state with specificity the grounds for your objection.

Objections and comments should be sent to Class Counsel at the address set forth below such that they are received no later than [42 days after the date of Preliminary Approval].

Lead Class Counsel
Hepatitis C Class Action Ciresi Conlin LLP 225 South Sixth Street, Suite 4600 Minneapolis, MN 55402

IV. NOTICE OF FINAL APPROVAL HEARING

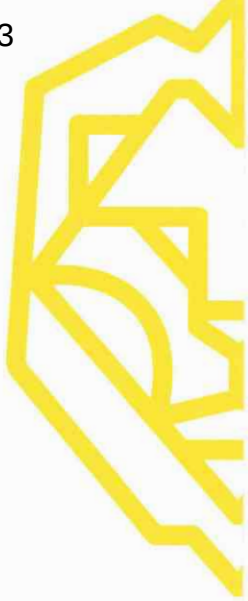
The Court will consider any objections or comments you may have regarding the Settlement Agreement, provided they are received by [42 days after the date of Preliminary Approval].

A hearing will be held on _____, at which the Court will consider the fairness of the Settlement Agreement and whether to approve it. Your objection will only be considered in writing and will not result in your presence in any hearing for testimony.

Dated: _____, 2019.

BY THE COURT:

Hon. Patrick J. Schiltz
United States District Judge
District of Minnesota



Ciresi Conlin LLP

[Date]

All prisoners with Untreated Chronic Hepatitis C
In the Minnesota Department of Corrections ("DOC")

Re: Settlement Agreement in Hepatitis C Class Action Lawsuit

Dear Member of the Plaintiff Class:

Our law firm represents prisoners in Minnesota Correctional facilities who have chronic hepatitis C and have not been treated with a direct-acting antiviral (DAA) medication. The Court approved a class defined as: "current and future inmates of Minnesota correctional facilities who have been diagnosed with chronic hepatitis C and have not received treatment with a direct-acting antiviral medication." We are writing to tell you about the Settlement Agreement (Agreement) with the DOC.

Beginning six months from the date the Court approves the Agreement, the DOC will expand its treatment with DAA medications to include the following prisoners who have chronic hepatitis C ("HCV"):

- Prisoners whose tests show they have stages F1, F2, F3 or F4 liver disease
- Prisoners at stage F0 who have other conditions including HIV, Hepatitis B, diabetes and various other conditions
- All prisoners at level F0 who have been in a DOC facility continuously for 16 months and have at least 24 more weeks to serve
- All untreated prisoners can be re-evaluated every 6 months and will be treated if their condition changes from stage F0 to F1.

Until then, the current treatment guidelines will remain in effect.

If you are satisfied with the Agreement, you do not need to do anything. If the Court approves the Settlement (at a hearing scheduled for [Date]), you will be entitled to treatment under its provisions.

If you have any objections to the Agreement, you must submit them to us in writing at the address below. If you have questions about the agreement, you can also write us. To be considered by the Court, objections are due on or before [Date]. We will not be able to answer questions about when you may be eligible for treatment because DOC health services staff will determine that based on testing results.

Hepatitis C Class Action
Ciresi Conlin LLP
225 South 6th Street, Suite 4600
Minneapolis, MN 55402

We are attaching a copy of the Notice of Settlement - please review it carefully. If you want to, you may also review the entire Agreement in the library of your facility.

We urge you to accept treatment when you are eligible. Treatment with DAAs cures HCV in most people and, if it is not treated, HCV can cause serious damage to your liver and other organs, and possibly death. You can also seek more information about HCV from health services providers at your facility.

We are pleased that we have been able to secure this Settlement Agreement on behalf of the class.

Sincerely,

Michael V. Ciresi
Katie Crosby Lehmann
Andrew H. Mohring
Esther O. Agbaje
Ciresi Conlin LLP
225 South 6th Street, Suite 4600
Minneapolis, MN 55402